REMARKS

Claims 1-16 are pending in the present application. Claims 1 and 5 have been amended.

Independent claim 1 has been amended to recite "a cover material adapted to be attached to skin in a manner covering over the entirety of a patch, comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, wherein said patch comprises a support film with a thickness of 12-30 μm and a drug-containing layer for contacting with the skin, said drug-containing layer being provided on one side of the support film, wherein said cover material is adapted to be attached to said support film and a region of the skin around said patch in such a manner that said pressure-sensitive adhesive layer contacts with the edges of said drug-containing layer, wherein said pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, and said pressure-sensitive adhesive layer of the cover material and said drug-containing layer are configured such that a drug contained in said drug-containing layer does not migrate into said pressure-sensitive adhesive layer." Support for amended claim 1 can be found, throughout the present specification and claims as originally filed, for example, in paragraphs [0010], [0032] and [0056] (Table 2).

Independent claim 5 has been amended to recite "a patch with cover material, comprising: a cover material comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, and a patch comprising a support film with a thickness of 12-30 μm and a drug-containing layer provided on one side of the support film, wherein the cover material and the patch are attached, with the other surface of said support film being in contact with said pressure-sensitive adhesive layer in such a manner that said pressure-sensitive adhesive layer remains around the periphery of said patch, and with said pressure-sensitive adhesive layer being in contact with the drug-containing layer exposed at the sides of said patch, wherein said pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, and said pressure-sensitive adhesive layer of the cover material and said drug-containing layer are configured such that a drug contained in said drug-containing layer does not migrate into said pressure-sensitive adhesive layer." Support for amended claim 5 can be found, for example, throughout the present specification and claims as originally filed, for example, in paragraphs [0010], [0032] and [0056] (Table 2).

No new matter has been added

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-10, 12 and 15 have been rejected under 35 USC § 112, first paragraph as failing to comply with the written description requirement.

The Examiner asserts that claims 1-10, 12 and 15 are "rejected on the grounds of new matter and written description." In particular, the Examiner is asserting that the examples in the specification do not support the members recited in the Markush claims.

Applicants respectfully traverse this rejection.

The Examiner asserts that "there is support for a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate *or* N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group on Page 2, paragraph 7, Page 3, paragraph 8, and Page 8, paragraph 28-Table 1, among others in the specification, but there is no support for a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate *and* N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group in the specification." *See* the Official Action at page 4.

Applicants respectfully note that the claim language "...the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group..." is permitted pursuant to **MPEP § 2173.05(h)**, which states that "...one acceptable form of alternative expression, which is commonly referred to as a Markush group, recites

members as being "selected from the group consisting of A, B ***and*** C." (emphasis added) *See Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

The Examiner has incorrectly concluded that the claim language recited in pending claims 1 and 5, in particular the use of the conjunction "and," requires that all the members recited in the Markush group be present together in a single formulation. Applicants respectfully submit that the use of the conjunction "and" within the context of a Markush group ***does not*** connote the use of all the members of the group together. Rather, "and" connotes the members comprising the single group. The language "...the first member being selected from the group consisting of," requires the selection of a single member of the group. Accordingly, Applicants respectfully submit that a single example in the instant specification employing all of the members recited in the Markush group is not required in order to satisfy the written description requirement within the meaning of 35 USC § 112, first paragraph.

In view of the foregoing, it is submitted that claims 1-10, 12 and 15 satisfy the written description requirement within the meaning of 35 USC § 112, first paragraph. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

II. At pages 4-9 of the Official Action, claims 1-10, 12 and 15 are rejected under 35 USC § 103(a) as being unpatentable over Tateishi et al. (WO 02/069942 and U.S. Patent Application No. 2004/0096491) in view of Liedtke (DE 3811564).

The Examiner asserts that it would have been obvious to incorporate the foamed polymer, cover layer and adhesive, as allegedly suggested by Liedtke, with the adhesive suggested by Tateishi, to obtain the presently claimed subject matter.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established because, whether taken alone or in combination, neither Tateishi et al. or Liedtke teach or suggest each and every limitation of the presently pending claims as required by *In re Wilson*.

Present claim 1 is directed to "a cover material adapted to be attached to skin in a manner covering over the entirety of a patch, comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, wherein said patch comprises a support film with a thickness of 12-30 μm and a drug-containing layer for contacting with the skin, said drug-containing layer being provided on one side of the support film, wherein said cover material is adapted to be attached to said support film and a region of the skin around said patch in such a manner that said pressure-sensitive adhesive layer contacts with the edges of said drug-containing layer, wherein said pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, and said pressure-sensitive adhesive layer of the cover material and said drug-containing layer are configured such that a drug contained in said drug-containing layer does not migrate into said pressure-sensitive adhesive layer." Claims 2-4 and 11-13 depend, either directly or indirectly from claim 1.

Present claim 5 is directed to "a patch with cover material, comprising: a cover material comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, and a patch comprising a support film with a thickness of 12-30 μm and a drug-containing layer provided on one side of the support film, wherein the cover material and the patch are attached, with the other surface of said support film being in contact with said pressure-sensitive adhesive layer in such a manner that said

pressure-sensitive adhesive layer remains around the periphery of said patch, and with said pressure-sensitive adhesive layer being in contact with the drug-containing layer exposed at the sides of said patch, wherein said pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer." Claims 6-10 and 14-16 depend, either directly or indirectly from claim 5.

In contrast, Tateishi et al. is directed to a patch agent having a support, and an adhesive layer laid on the support and containing an adhesive base and a drug, wherein the adhesive base contains an acrylic polymer substantially having no carboxyl and no hydroxyl in molecules thereof, and a rubber-based polymer. *See* Tateishi et al. at the Abstract. However, Tateishi et al. do not teach or suggest the presently claimed cover material or patch with cover material, which cover material, as described above, is adapted to be attached to skin in a manner covering over the entirety of a patch, comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, wherein said patch comprises a support film with a thickness of 12-30 μm and a drug-containing layer for contacting with the skin, said drug-containing layer being provided on one side of the support film, wherein said cover material is adapted to be attached to said support film and a region of the skin around said patch in such a manner that said pressure-sensitive adhesive layer contacts with the edges of said drug-containing layer, and wherein said pressure-sensitive adhesive

layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, and said pressure-sensitive adhesive layer of the cover material and said drug-containing layer are configured such that a drug contained in said drug-containing layer does not migrate into said pressure-sensitive adhesive layer, as presently claimed.

Therefore, Applicants submit that Tateishi et al. do not teach or suggest every element of the presently pending subject matter.

Liedtke does not remedy the deficiencies of Tateishi et al. Liedtke is directed to improving the absorption of medicaments by forming a plaster of a support of an open-cell, elastic foam having technically produced recesses of different geometries for the reception of drug formulations, a mechanical separating layer on the upper side facing away from the skin and an adhesive tape of an elastic closed-cell foam. The support and adhesive edge are bonded on the top side with an elastic covering film, which contains a peelable protective film on the lower side. *See* Liedtke, Abstract. Like Tateishi et al., Liedtke does not teach or suggest the presently claimed cover material or patch with cover material. Additionally, Liedtke does not teach or suggest a patch having a support film with a thickness of 12-30 μm. Further, Liedtke does not teach or suggest a patch wherein the drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer.

Applicants respectfully submit that, whether taken alone or in combination, neither of Tateishi et al. or Liedtke teach or suggest every element of the presently pending subject matter. Accordingly, Tateishi et al. and Liedtke do not render the presently pending claims obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At pages 9-11 of the Official Action, claims 1-2, 4-7, 9-10, 12 and 15 have been rejected under 35 USC § 103 as being unpatentable over Arth et al. (US Patent No. 6,461,636) in view of Terahara et al. (WO 03/013611).

The Examiner appears to assert that it would have been obvious to substitute the copolymers/polymers of the contact adhesive film of Arth et al. with the copolymers/polymers of Terahara et al. to arrive at the presently claimed subject matter.

Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is discussed above in Section II.

A proper case of obviousness under 35 U.S.C. §103, requires that the prior art as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir.1988).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of

success. In addition, the prior art reference or references when properly combined, must teach or suggest all the claim limitations.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a proper case of *prima facie* obviousness has not been established because there is no suggestion or motivation to modify the teachings of Arth et al. with the teachings of Terahara et al. However, assuming *arguendo*, such motivation exists, neither Arth et al. nor Terahara et al., whether taken alone or together, teach or suggest every element of the presently pending claims.

A. No Motivation to Modify

Applicants respectfully submit that there is no motivation to modify the transdermal system of Arth et al. with the patch disclosed by Terahara et al. because the patch according to Terahara et al. comprises a drug containing layer that is also the adhesive layer. In contrast, Arth et al. discloses a distinct polymer layer containing the active substance and a distinct adhesive film layer. As known to those skilled in the art, the inclusion of specific adhesive monomers included in a patch's drug containing layer may affect drug delivery and therefore bioavailability. Accordingly, modifying the transdermal system of Arth et al. with the drug containing layer of Terahara et al. may render the system unsatisfactory for its intended use. Accordingly, Applicants respectfully submit that there is no motivation to modify the teachings of Arth et al. with the teachings of Terahara et al.

B. All Elements Not Taught or Suggested

Independent claim 1 is discussed above in regard to the previous rejection. Claims 2, 4 and 11-13 depend, either directly or indirectly from claim 1.

Independent claim 5 is discussed above in regard to the previous rejection. Claims 6, 7, 9 and10 depend, either directly or indirectly from claim 5.

Neither Arth et al. nor Terahara et al. teach or suggest a cover material or a patch with cover material, where the pressure-sensitive adhesive layer of the cover material and the drug-containing layer are configured such that a drug contained in the drug-containing layer does not migrate into the pressure-sensitive adhesive layer, as presently claimed.

In contrast to the presently claimed subject matter, Arth et al. is directed to a transdermal therapeutic system for the transcutaneous administration of pergolide over several days and to a method for its manufacture without using solvents. *See* Arth et al., Abstract. The transdermal system described in Arth et al. contains a carrier foil, a contact adhesive film, an inner covering foil, a drug containing polymer matrix layer having no adhesive, and a detachable protective foil.

However, Arth et al. do not teach or suggest a drug containing layer comprising an acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, where the pressure-sensitive adhesive layer of the cover material and the drug-containing layer are configured such that a drug contained in the drug-containing layer does not migrate into the pressure-sensitive adhesive layer, as presently claimed. Further, Arth et al. does not teach or suggest a patch wherein the drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block

copolymer. Therefore, Applicants submit that Arth et al. do not teach or suggest every element of the presently pending subject matter.

Terahara et al. do not remedy the deficiencies of Arth et al. Terahara et al. is directed to external preparations for percutaneous application and compositions whereby a drug having an ergoline skeleton can be effectively absorbed via the skin into the blood under circulation while reducing selected side effects. *See* Terahara et al., Abstract. The transdermal system described in Terahara et al. contains a support layer comprised of an elastic or a non-elastic body, a drug-containing nonaqueous type matrix layer comprised of an acrylic polymer or a rubber polymer, and a liner.

Like Arth et al., Terahara et al. do not teach or suggest a cover material or a patch with cover material, where the pressure-sensitive adhesive layer of the cover material and the drug-containing layer are configured such that a drug contained in the drug-containing layer does not migrate into the pressure-sensitive adhesive layer, as presently claimed. Additionally, Terahara et al. do not teach or suggest a patch having a support film with a thickness of 12-30 μm. Accordingly, Applicants submit that, whether taken alone or in combination, neither of Arth et al. or Terahara et al. teach or suggest every element of the presently claimed subject matter.

Further, according to the presently claimed subject matter, migration of the drug into the pressure-sensitive adhesive layer is prevented when the pressure-sensitive adhesive layer is in contact with the drug containing layer. The aforementioned effect is the result of specific make-up of the present specific pressure-sensitive adhesive layer. As described at paragraph 10 of the present specification, due to these properties, the presently claimed cover material and patch provide effective drug release because the

drug becomes concentrated on the skin, and the percutaneous absorption of the drug is therefore enhanced. *See* Example 1 at paragraphs [0055] to [0057] of the present published specification. Applicants note that such effects are not taught or suggested by either of Arth et al. or Terahara et al.

Specifically, Applicants note that with regard to the drug containing layer of Terahara et al., Terahara et al. describes that even a minimally soluble drug, such as pergolide mesylate, dissolves well in a composition comprising a copolymer of monomers similar to those used in the pressure-sensitive adhesive layer of the presently claimed cover material. *See* paragraphs 10, 16, 17 and 25 of Terahara et al. In this regard, Applicants note that from the disclosure of Terahara et al., those skilled in the art would predict that drugs comprised in the drug-containing layer of Terahara et al., including pergolide mesylate, would easily migrate into the presently claimed pressure-sensitive adhesive layer of the cover material. Therefore, Applicants submit that the effects achieved by the presently claimed subject matter are not predictable by the disclosure of Terahara et al.

Applicants respectfully submit that, whether taken alone or in combination, neither of Arth et al. or Terahara teach or suggest every element of the presently pending subject matter. Accordingly, Arth et al. and Terahara et al. do not render the presently pending claims obvious within the meaning of 35 USC § 103 (a). Thus, the Examiner is respectfully requested to withdraw this rejection.

IV. At pages 11-13 of the Official Action, claims 3 and 8 have been rejected under 35 USC § 103 as being unpatentable over Arth et al. in view of Terahara et al. as in claims 1, 2, 4-7, 9, and 10, and further in view of Liedtke.

The Examiner asserts that it would have been obvious to incorporate the foam polymer described in Liedtke with the cover layer and adhesives disclosed with Arth et al. and Terahara et al.

Applicant respectfully traverses this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is set forth above.

Independent claim 1 is discussed above in regard to the previous rejection. Claims 3 and 11-13 depend, either directly or indirectly from claim 1.

Independent claim 5 is discussed above in regard to the previous rejection. Claims 8 and 14-16 depend, either directly or indirectly from claim 5.

Each of Arth et al., and Terahara et al. and are discussed in detail above with regard to the previous rejections. As discussed, Applicants submit that there is no motivation to modify the transdermal system of Arth et al. with the patch disclosed by Terahara et al. because the patch according to Terahara et al. comprises a drug containing layer that is also the adhesive layer.

Additionally, whether taken alone or in combination, Applicants submit that neither Arth et al. nor Terahara et al. teach or suggest every element of the present subject matter as required to establish a *prima facie* case of obviousness.

Liedtke does not remedy the deficiencies of Arth et al. and Terahara et al., because Liedtke et al. does not teach or suggest the presently claimed cover material or

patch with cover material, which cover material, as described above, is adapted to be attached to skin in a manner covering over the entirety of a patch, comprising a support layer and a pressure-sensitive adhesive layer provided on one side of the support layer, wherein said patch comprises a support film with a thickness of 12-30 μm and a drug-containing layer for contacting with the skin, said drug-containing layer being provided on one side of the support film, wherein said cover material is adapted to be attached to said support film and a region of the skin around said patch in such a manner that said pressure-sensitive adhesive layer contacts with the edges of said drug-containing layer, wherein said pressure-sensitive adhesive layer comprises a pressure-sensitive adhesive obtained by polymerizing a first and a second monomer, the first monomer being selected from the group consisting of vinyl acetate and N-vinyl-2-pyrrolidone and the second monomer being a (meth)acrylic acid alkyl ester with a C8 alkyl group, and wherein said drug-containing layer comprises acrylic pressure-sensitive adhesive and styrene-isoprene-styrene block copolymer, and said pressure-sensitive adhesive layer of the cover material and said drug-containing layer are configured such that a drug contained in said drug-containing layer does not migrate into said pressure-sensitive adhesive layer, as presently claimed. Therefore, Applicants submit that, whether taken alone or in combination, Arth et al., Terahara et al. and Liedtke do not teach or suggest every element of the presently pending subject matter.

In view of the remarks set forth herein, it is submitted that, whether taken alone or in combination, Arth et al., Terahara et al. and Liedtke do not render the presently pending claims obvious within the meaning of 35 USC § 103 (a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

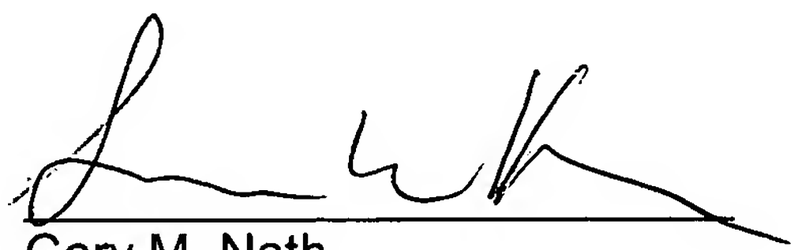
CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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